DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–4491]

FDA's Proposed Strategy on Reuse of Single Use Devices; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled ''FDA's Proposed Strategy on Reuse of Single-Use Devices.'' The document presents the agency's current thinking about the best way to address the concerns regarding the practice of reprocessing and reusing devices that are labeled, or otherwise intended, for one use only (referred to as ''single use devices'' (SUD's)). The strategy outlined in the document is based, in part, on information and suggestions the agency received during the May 5 and 6, 1999, conference on Reuse of Single-Use Devices, which the agency cosponsored with the Association for the Advancement of Medical Instrumentation (AAMI). The document reflects FDA's belief that the optimum approach to this issue will involve action by the agency and all of the affected stakeholders. The agency is soliciting comments, proposals for alternative approaches, and information on this issue. In a future issue of the **Federal Register**, the agency will announce an open meeting, to be held in Rockville, Maryland on December 14, 1999, to gather comments on the agency's proposed strategy.

DATES: Submit written comments at anytime.

ADDRESSES: See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the document. Submit written requests for single copies (on a 3.5″ diskette) of ''FDA's Proposed Strategy on Reuse of Single-Use Devices'' to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350

Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. Submit written comments concerning ''FDA's Proposed Strategy on Reuse of Single-Use Devices'' to the Dockets Management Branch, (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Larry D. Spears, Center for Devices and Radiological Health (HFZ–340), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 301–594–4646.

SUPPLEMENTARY INFORMATION:

I. Background

Reuse of SUD's is the practice of cleaning, disinfecting, sterilizing, and reusing medical devices that are intended for only one use. Reuse has raised concerns regarding patient safety, informed consent, and equitable regulation of reuse under the Federal Food, Drug, and Cosmetic Act. On May 5 and 6, 1999, FDA and AAMI cosponsored a conference on Reuse of Single-Use Devices to help examine policy alternatives regarding the practice of reuse. At that time, the agency committed to publishing a response to the positions expressed at the conference in the **Federal Register** by no later than October 1999. ''FDA's Proposed Strategy on Reuse of Single-Use Devices'' is that response.

II. Significance of the Proposed Strategy Document

''FDA's Proposed Strategy on Reuse of Single-Use Devices'' represents options that the agency is considering on the reuse of single-use devices.

III. Electronic Access

In order to receive ''FDA's Proposed Strategy on Reuse of Single-Use Devices'' via your fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from

a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at the second voice prompt press 2, and then enter the document number 2525 followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of ''FDA's Proposed Strategy on Reuse of Single-Use Devices'' may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Internet. Updated on a regular basis, the CDRH home page includes ''FDA's Proposed Strategy on Reuse of Single-Use Devices,'' device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at http://www.fda.gov/cdrh.

IV. Comments

Interested persons may, at any time, submit to the Dockets Management Branch (address above) written comments regarding this document. Submit two copies of any comments, except that individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document. The agency will consider such comments when

determining their final strategy. ''FDA's Proposed Strategy on Reuse of Single-Use Devices'' and any received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 10-28-99

October 28, 1999

Margaret M. Dotzel
Acting Associate Commissioner for Policy

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